

REMARKS

This Response addresses the Office Action mailed on November 30, 2004. Claims 5, 8, 9, 11, 15, 19, 21, 23, 24, 26, 30, 31, 35, 36, 38 and 48 have been amended. The Specification has been amended to correct a grammatical error. The amendments are supported by the Specification. No new matter has been presented.

Claim Rejections - 35 U.S.C. § 112**A. Claims 2-5, 7, 15-17, 21, 23-25, 27, 32, 39, 42 and 44-48**

Claims 2-5, 7, 15-17, 21, 23-25, 27, 32, 39, 42 and 44-48 have been rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. The Examiner has found that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, possessed the claimed invention. In particular, the Examiner has rejected the claims because “[t]here is no support in the specification as originally filed for the expression ‘first layer’ or ‘second layer.’”

35 U.S.C. Section 112, first paragraph, requires the applicant to “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). An applicant can describe the invention “by such descriptive means as words, structures, figures, diagrams, formulas, etc.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). In fact, drawings alone “may provide a ‘written description’ of an invention as required by § 112.” *Vas-Cath*, 935 F.2d at 1565. However, to satisfy the written description requirement, “the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.” *Crown Operations Int’l v. Krone*, 289 F.3d 1367, 1376 (Fed. Cir. 2002); see also, *Lockwood*, 107 F.3d at 1572. In other words, **the specific words in the claims do not**

have to be present in the specification as filed to provide support for the claimed subject matter at issue.

Applicant respectfully submits that the application as filed conveyed with reasonable clarity to those skilled in the art that Applicant was in possession of the invention as of the filing date of the original disclosure. Although the specific words “first layer” or “second layer” are not found in the original specification, there is sufficient support in the specification for a coating that has multiple layers of material including a “first layer” and a “second layer.” There is at least sufficient support in Figures 2A-2E which show multiple layers of material. For example, Figure 2B shows four layers of material. It can be said that Figure 2B therefore shows a “first layer,” a “second layer,” a “third layer” and a “fourth layer.” As noted above, the Federal Circuit has ruled that drawings alone “may provide a ‘written description’ of an invention as required by § 112.” *Vas-Cath*, 935 F.2d at 1565.

Furthermore, the text of the Specification provides ample support for the terms “first layer” and “second layer.” For example, on pages 11 and 12 of the Specification, Figures 2A-2C are described as showing “multi-layered” polymeric coatings. Moreover, on page 15, layer 5 is described in a generic sense: “[t]he polymer in layer 5 is typically one of the polymers commonly used for making topcoats. The layer 5 includes an [*sic*] compound which makes the layer 5 non-transparent.” Layer 6 is similarly described on page 17: “[t]he amount of solids in the layer 6 (the compound plus the polymer) can be between about 0.25% (mass) and about 20% (mass) of the solution to be applied to form the layer 6.”

In short, Applicant notes that although the Specification primarily describes each of the layers in terms of its respective functionality, there is sufficient support for more generic modifiers such as “first” and “second” within the drawings and the text of the Specification. Accordingly, please reconsider and remove the Section 112 rejection.

B. Claim 26

Claim 26 has been rejected under 35 U.S.C. Section 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner has found that “Claim 26 is vague because it is not clear what the recitation of ‘wherein at least of the layers of the coating material includes a polymer.’”

In relevant part, Applicants have amended Claim 26 to read, “wherein at least one of the layers of the coating material includes a polymer.” Accordingly, the Section 112 rejection should be removed.

Claim Rejections – 35 U.S.C. § 102**A. THE EXAMINER’S FINDING IS NOT SUFFICIENT TO CONCLUDE THAT THE PRIOR ART ANTICIPATES THE PRESENT INVENTION.**

Claims 2-5, 7-11, 14, 19, 21, 25, 31, 36-38 and 40 have been rejected under 35 U.S.C. Section 102(e) as being anticipated by Harish et al. (U.S. Patent Application No. 2002/0122877 A1). Harish et al. is directed to a method of forming a polymeric coating on a stent. The Harish et al. method includes forming a polymeric sheath that may contain a drug, inserting a stent into the sheath, and then heat treating the sheath so that the sheath is converted into a polymeric coating disposed on the stent. *See generally* paragraphs 35, 40 and 41.

According to the Examiner, Harish et al. is “still relevant to the claims because Harish discloses coating layers that have active agents such as paclitaxel, docetaxel, actinomycin and vincristine. The coating composition also contains radiopaque elements such as gold.” Applicant respectfully submits that this finding is certainly not sufficient to conclude that the Harish et al. reference **anticipates** the present invention. As the Federal Circuit has made clear, simply finding that a reference is “relevant” is not enough.

B. ANTICIPATION REQUIRES THAT EVERY ELEMENT OF THE CLAIMED INVENTION IS LITERALLY PRESENT IN THE PRIOR ART, AS ARRANGED IN THE CLAIM.

According to the Federal Circuit, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). In order for the reference to anticipate an invention, “[e]very element of the claimed invention must be literally present, **arranged as in the claim**” and the **“identical invention must be shown in as complete detail as is contained in the patent claim.”** *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (citations omitted) (emphasis added)¹. At the very least, the Examiner has failed to show that every element of the claimed invention is literally present.

C. HARISH ET AL. DOES NOT DISCLOSE A MULTIPLE LAYERED COATING INCLUDING A LIGHT/UV-PROTECTIVE LAYER DISPOSED OVER A DRUG LAYER.

With regard to independent Claims 5, 8 and 19, Harish et al. clearly does not disclose a final coating for a medical device that includes **multiple layers** where a drug reservoir layer is covered by a layer that includes a compound that is capable of absorbing radiation having a wavelength in the UV and/or visible light spectrum. Without this exact coating structure, it can not be said that the prior art **anticipates** the present invention.

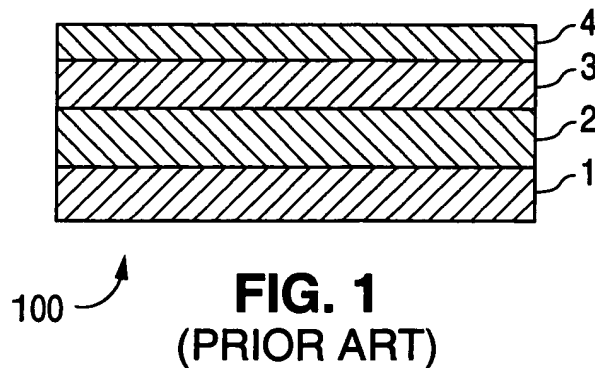
Although Harish et al. discloses that the composition for forming polymeric sheath 24 can contain a radiopaque element such as gold (*see* paragraph 34), there is nothing in Harish et al. that discloses the precise coating structure of the present invention. In the section entitled, “Composition for Forming a Sheath” Harish et al. discloses:

Sufficient amounts of radiopaque elements or radioactive isotopes may be **dispersed** in the composition. By dispersed it is meant that the substances are **not present in the composition as agglomerates or flocs**. In some compositions, certain substances will

¹ See also, *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1459 (Fed. Cir. 1984) (holding that the district court’s finding of anticipation was mistaken and clearly erroneous because “[t]he district court’s analysis treated the claims as mere catalogs of separate parts, in disregard of the **part-to-part relationships** set forth in the claims and that give the claims their meaning”) (emphasis added).

disperse with ordinary mixing. Otherwise, the substances can be dispersed in the composition by high shear processes such as ball mill, disc mill, sand mill, attritor, rotor stator mixer, or ultrasonication--all such high shear dispersion techniques being well known to one of ordinary skill in the art.

Paragraph 34 on page 4. This section clearly contemplates that the radiopaque elements such as gold **should not be aggregated or formed into a layer** within the coating. Moreover, under a separate section entitled "Optional Topcoat," Harish et al. discloses that in some embodiments, "a second polymeric coating, or topcoat, is formed onto at least a portion of coating 26 on stent 10." Paragraph 49 on page 5. There is nothing in Harish et al. that suggests that the "optional topcoat" should include the radiopaque element. These two sections taken together clearly suggest that the radiopaque element **should only be dispersed within the drug-sheath portion of the device and not the protective outer coating**. For example, referring to the figure below (which corresponds to Figure 1 of the present application (labeled as Prior Art)), Harish et al. merely discloses a stent (1) that includes a coating comprising a drug-polymer layer (3) containing radiopaque elements and an optional polymer topcoat layer (4) covering the drug-polymer layer (3).



So, Harish et al. merely discloses a prior art stent coating. It therefore cannot be said that Harish et al. disclose the present invention, i.e., a multiple layered coating including a light/UV-protective layer disposed over a drug layer.

D. HARISH ET AL. DOES NOT DISCLOSE ALL OF THE ELEMENTS OF CLAIM 5.

The Examiner has indicated on the record that “[r]egarding the mass ratio’s [*sic*], the rejection of those claims having the mass ratios . . . **are not included in the 102 rejection.**

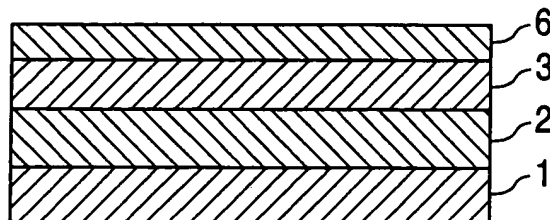
Although, applicants argue that Harish fails to disclose the mass ratios, applicants provided no demonstration that the mass ratios and the thickness of any of the layers provides unusual results since mass ratios and thicknesses would be **obvious variation.**” Claim 5 claims in relevant part “the mass ratio between the light- and/or UV-protective compound and the polymer in the second layer is between about 3:1 and about 1:3.” As the Examiner has already indicated, all of the claims that include mass ratio limitations are not anticipated by Harish et al. Since Claim 5 includes a mass ratio limitation, it should not be rejected under Section 102. Applicant therefore respectfully requests the Examiner to remove the Section 102 rejection.

Moreover, Harish et al. also fails to disclose the coating structure as claimed in Claim 5.

In particular, Harish et al. fail to disclose a coating for a medical device, comprising:

- (a) a first layer including a drug and a polymer;
- (b) a second layer including a polymer disposed over the first layer; and
- (c) a light- and/or UV-protective compound included in the second layer.

For example, referring to the figure below which corresponds to Figure 2B of the present application, Harish et al. does not disclose a first layer (3) including a drug and a polymer that is covered by a second layer (6) that includes a light- and/or UV-protective compound.

**FIG. 2B**

As explained above, Harish et al. merely discloses radiopaque elements such as gold that are dispersed in the same layer as the drug.

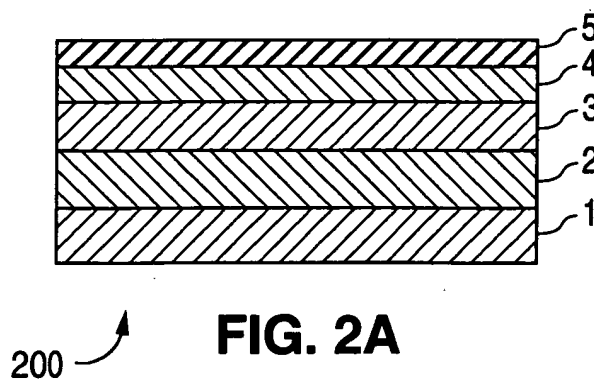
Because Harish et al. does not disclose all of the limitations of Claim 5, Claim 5 should be allowable over Harish et al. Claims 2-4, 7, 11 and 25 depend from Claim 5 and should be allowable for at least the same reason.

E. HARISH ET AL. DOES NOT DISCLOSE ALL OF THE ELEMENTS OF CLAIM 8.

Harish et al. fails to disclose the coating structure as claimed by Claim 8. In particular, Harish et al. at least fails to disclose a coating for a medical device comprising:

- (a) a drug layer including a drug and a polymer;
- (b) a topcoat layer disposed over the drug layer, wherein the topcoat layer is free from any drugs; and
- (c) a film-forming layer disposed over the topcoat layer, wherein a light- and/or UV-protective compound is included in the film-forming layer.

For example, referring to the figure below which corresponds to Figure 2A of the present application, Harish et al. does not disclose a drug layer (3) that is covered by a topcoat layer (4) that is in turn is covered by a film-forming layer (5) that includes a light- and/or UV-protective compound.



Because Harish et al. fails to disclose each and every element of the claimed invention as arranged as Claim 8, Claim 8 should be found allowable. Claims 36 and 40 depend from Claim 8 and should be allowed for at least the same reason.

F. HARISH ET AL. DOES NOT DISCLOSE ALL OF THE ELEMENTS OF CLAIM 9.

It appears that the Examiner has mistakenly indicated that Claim 9 is rejected under Section 102. According to the Examiner Claim 33 is allowable, presumably because it recites that “the mass ratio between the drug, the light- and/or UV-protective compound and the polymer is between about 1:1:2 and about 1:3:20.” Claim 9 includes these same limitations and therefore should be allowed. Applicant respectfully requests the Examiner to clearly indicate that Claim 9 is also allowable. Claims 10, 14 and 31 depend from Claim 9 and should also be found allowable.

G. HARISH ET AL. DOES NOT DISCLOSE ALL OF THE ELEMENTS OF CLAIM 19.

Harish et al. also fails to disclose all of the limitations of Claim 19, and specifically fails to disclose a method for fabricating a medical article, including forming a coating on a medical device, wherein the coating comprises:

a drug layer including a drug and a polymer, a topcoat layer disposed over the drug layer, the topcoat layer being free from any drugs, and a film-forming layer disposed over the topcoat layer, wherein a light- and/or UV-protective compound is included in the film-forming layer.

As explained above for Claim 8, Harish et al. does not disclose a coating structure that includes a drug layer, a topcoat layer and a film-forming layer having a light- and/or UV-protective compound. Because Harish et al. fails to disclose a method of forming a coating where the coating is **arranged** as set forth in Claim 19, Claim 19 should be found allowable. Claims 37 and 38 depend from Claim 19 and should be allowed for at least the same reason.

H. CONCLUSION

In short, the Examiner has erroneously disregarded the “part-to-part relationship” as set forth by the claimed invention. Although Harish et al. may disclose some of the individual parts or limitations of the claims, it does not appreciate the specific arrangement of the coating, and in particular, the relationship of the component layers. As such, it cannot be said that the device

described in Harish et al. is identical to the claimed invention. Therefore, the Examiner must remove the Section 102 rejection.

Claim Rejections – 35 U.S.C. § 103

The Examiner has rejected Claims 15-17, 21, 23-27, 32, 42 and 45 under 35 U.S.C. § 103(a) as being unpatentable over Harish et al. Effective November 29, 1999, subject matter which was prior art under former 35 U.S.C. Section 103 via 35 U.S.C. §102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention, “were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.” *See* MPEP Section 706.02(I)(1). A statement of an attorney of record can be sufficient evidence to establish common ownership. *See* MPEP Section 706.02(I)(2).

As established by the enclosed Statement of Common Ownership, at the time the invention of the current application was made, the inventions of the current application and Harish et al. (U.S. Patent Application No. 2002/0122877 A1) were owned by, or subject to an obligation of assignment to, Advanced Cardiovascular Systems, Inc., a California corporation. Since Applicant has established common ownership, Harish et al. is disqualified as prior art and should be removed as a reference. Applicant therefore respectfully requests the Examiner to allow the claims.

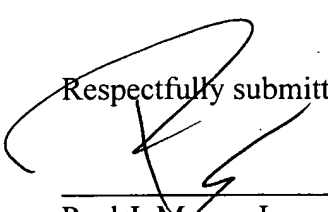
CONCLUSION

Claims 2-5, 7-11, 14-17, 19, 21 and 23-48 are pending in this application. Examination and allowance of the claims is respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned at (415) 954-0345.

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